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Federal Agencies

June 17, 2003

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**Art Unit 1634**

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JUN 18 2003

**TECH CENTER 1600/2900**

Re: U.S. Utility Patent Application  
Appl. No. 09/517,466; Filed: March 2, 2000  
For: **Compositions and Methods for Use in Recombinational  
Cloning of Nucleic Acids**  
Inventors: HARTLEY *et al.*  
Our Ref: 0942.4680003/RWE/BJD/JKM

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Third Supplemental Information Disclosure Statement;
2. List of cited references on Form PTO-1449 (34 sheets);
3. A copy of each reference cited on Form PTO-1449 (118 documents: **AL6-AL9, and AR71-AT104**); and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
June 17, 2003  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Brian J. Del Buono", written over a horizontal line.

Brian J. Del Buono  
Attorney for Applicants  
Registration No. 42,473

RWE/BJD/JKM/acr  
Enclosures

SKGF\_DC1:138771.1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Hartley *et al.*

Appl. No. 09/517,466

Filed: March 2, 2000

For: **Compositions and Methods for  
Use in Recombinational  
Cloning of Nucleic Acids**

Confirmation No. 4289

Art Unit: 1634

Examiner: Johannsen, D.

Atty. Docket: 0942.4680003/RWE/BJD/JKM

**Third Supplemental Information Disclosure Statement**

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P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Third Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' First Supplemental Information Disclosure Statement filed on April 20, 2001, and Applicants' Second Supplemental Information Disclosure Statement, filed electronically herewith, in connection with the above-captioned application. A copy of each document is also provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates

should not be construed as an admission that the information was actually published on the date indicated.

This Third Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Brian J. Del Buono  
Attorney for Applicants  
Registration No. 42,473

Date: June 17, 2003

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FORM PTO-1449  THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0942.4680003/RWE/BJD/JKM	APPLICATION NO. 09/517,466
	APPLICANT Hartley et al.	
	FILING DATE March 2, 2000	GROUP 1634

## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL6	EP 0 220 009	04/29/1987	Europe			Yes No
	AM6	WO 90/11375	10/04/1990	WIPO			Yes No
	AN6	EP 0 427 074	05/15/1991	Europe			Yes No
	AO6	WO 91/09957	07/11/1991	WIPO			Yes No
	AP6	WO 92/15694	09/17/1992	WIPO			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>71</u>	Akagi, K., et al., "Cre-mediated somatic site-specific recombination in mice," <i>Nucl. Acids Res.</i> 25:1781-1788, Oxford University Press (1997).
	AS	<u>71</u>	Aladjem, M.I., et al., "Positive Selection of FLP-Mediated Unequal Sister Chromatid Exchange Products in Mammalian Cells," <i>Mol. Cell. Biol.</i> 17:857-861, American Society for Microbiology (1997).
	AT	<u>71</u>	Angelastro, J.M., et al., "Identification of diverse nerve growth factor-regulated genes by serial analysis of gene expression (SAGE) profiling," <i>Proc. Natl. Acad. Sci. USA</i> 97:10424-10429, National Academy of Sciences (September 2000).

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	AL7	WO 92/22650	12/23/1992	WIPO			Yes No
	AM7	EP 0 542 466	05/19/1993	Europe			Yes No
	AN7	WO 94/03624	02/17/1994	WIPO			Yes No
	AO7	WO 94/18333	08/18/1994	WIPO			Yes No
	AP7	WO 96/04393	02/15/1996	WIPO			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	72	Angrand, P.O., et al., "Inducible expression based on regulated recombination: a single vector strategy for stable expression in cultured cells," <i>Nucl. Acids Res.</i> 26:3263-3269, Oxford University Press (July 1998).
	AS	72	Ayres, E.K., et al., "Precise Deletions in Large Bacterial Genomes by Vector-mediated Excision (VEX). The trfA Gene of Promiscuous Plasmid RK2 is Essential for Replication in Several Gram-negative Hosts," <i>J. Mol. Biol.</i> 230:174-185, Academic Press (1993).
	AT	72	Backman, K., et al., "Use of Synchronous Site-Specific Recombination In Vivo to Regulate Gene Expression," <i>Bio/Technology</i> 2:1045-1049, Nature Publishing Company (1984).

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	AL8	WO 96/30498	10/03/1996	WIPO			Yes No
	AM8	WO 96/40724	12/19/1996	WIPO			Yes No
	AN8	WO 00/60091	10/12/2000	WIPO			Yes No
	AO8	WO 01/07572	02/01/2001	WIPO			Yes No
	AP8	WO 01/62892	08/30/2001	WIPO			Yes No

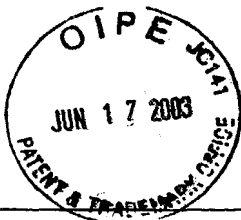
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	73	Bai, C., et al., "SKP1 Connects Cell Cycle Regulators to the Ubiquitin Proteolysis Machinery through a Novel Motif, the F-Box," Cell 86:263-274, Cell Press (1996).
	AS	73	Bernard, P., et al., "The F Plasmid CcdB Protein Induces Efficient ATP-dependent DNA Cleavage by Gyrase," J. Mol. Biol. 234:534-541, Academic Press (1993).
	AT	73	Boshart, M., et al., "A Very Strong Enhancer is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," Cell 41:521-530, The MIT Press (1985).

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	AL9	WO 02/05294	01/17/2002	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

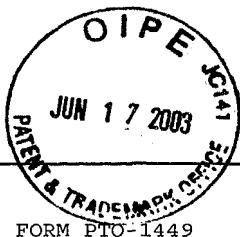
AR	74	Bouhassira, E.E., et al., "Transcriptional Behavior of LCR Enhancer Elements Integrated at the Same Chromosomal Locus by Recombinase-Mediated Cassette Exchange," <i>Blood</i> 90:3332-3344, The American Society of Hematology (1997).
AS	74	Burioni, R., et al., "An improved phage display vector for antibody repertoire cloning by construction of combinatorial libraries," <i>Res. Virol.</i> 148:161-164, Elsevier (1997).
AT	74	Capone, J.P., et al., "Introduction of UAG, UAA, and UGA Nonsense Mutations at a Specific Site in the <i>Escherichia coli</i> Chloramphenicol Acetyltransferase Gene: Use in Measurement of Amber, Ochre, and Opal Suppression in Mammalian Cells," <i>Mol. Cell. Biol.</i> 6:3059-3067, American Society for Microbiology (1986).

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	75	Chanock, R.M., et al., "Human Monoclonal Antibody Fab Fragments Cloned from Combinatorial Libraries: Potential Usefulness in Prevention and/or Treatment of Major Human Viral Diseases," <i>Infect. Agents Dis.</i> 2:118-131, Raven Press (1993).
AS	75	Chong, S., et al., "Single-column purification of free recombinant proteins using a self-cleavable affinity tag derived from a protein splicing element," <i>Gene</i> 192:271-281, Elsevier Science B.V. (1997).
AT	75	Choulika, A., et al., "Transfer of Single Gene-Containing Long Terminal Repeats into the Genome of Mammalian Cells by a Retroviral Vector Carrying the cre Gene and the loxP Site," <i>J. Virol.</i> 70:1792-1798, American Society for Microbiology (1996).

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	76	Chuang, C.-F., et al., "Specific and heritable genetic interference by double-stranded RNA in <i>Arabidopsis thaliana</i> ," <i>Proc. Natl. Acad. Sci. USA</i> 97:4985-4990, National Academy of Sciences (April 2000).
	AS	76	Cigan, A.M., et al., "Mutational Analysis of the <i>HIS4</i> Translational Initiator Region in <i>Saccharomyces cerevisiae</i> ," <i>Mol. Cell. Biol.</i> 8:2964-2975, American Society for Microbiology (1988).
	AT	76	CLONTECH, "Creator™ Gene Cloning & Expression System," <i>CLONTECHniques</i> 15:7-11, CLONTECH, (April 2000).

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	77	CLONTECH, "New Additions to the Creator™ Platform," CLONTECHniques 16:4 pages, CLONTECH, (January 2001).
	AS	77	CLONTECH, "New Creator™ -Compatible Expression Systems," CLONTECHniques 15:2 pages, CLONTECH, (October 2000).
	AT	77	CLONTECH, "Creator™ Acceptor Vector Construction Kit" CLONTECHniques 16:2 pages, CLONTECH, (October 2001).

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	AR	78	CLONTECH, "Creator™ SMART™ Library Construction Kit," CLONTECHniques 16:2 pages, CLONTECH, (October 2001).
	AS	78	CLONTECH, "Creator™: The Universal Platform for Analysis of Gene Function," Powerpoint Presentation, 9 pages, CLONTECH, (July 24, 2001), available at <a href="http://www.clontech.com/products/families/creator/popups/slpage1.html">http://www.clontech.com/products/families/creator/popups/slpage1.html</a> .
	AT	78	CLONTECH, "Creator™ pDNR-Dual Cloning Kit," CLONTECHniques 16:3 pages, CLONTECH, (October 2001).

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AR	79	Curcio, M.J., and Garfinkel, D.J., "Single-step selection for Tyl element retrotransposition," <i>Proc. Natl. Acad. Sci. USA</i> 88:936-940, National Academy of Sciences (1991).
AS	79	Datson, N.A., et al., "MicroSAGE: a modified procedure for serial analysis of gene expression in limited amounts of tissue," <i>Nucl. Acids Res.</i> 27:1300-1307, Oxford University Press (March 1999).
AT	79	Davis, C.R., et al., "Analysis of the Mechanisms of Action of the <i>Saccharomyces cerevisiae</i> Dominant Lethal <i>cdc42</i> <sup>G12V</sup> and Dominant Negative <i>cdc42</i> <sup>D118A</sup> Mutations," <i>J. Biol. Chem.</i> 273:849-858, The American Society for Biochemistry and Molecular Biology, Inc. (January 1998).

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	AR	80	Deng, M.-D., and Coleman, J.R., "Ethanol Synthesis by Genetic Engineering in Cyanobacteria," <i>Appl. Environ. Microbiol.</i> 65:523-528, American Society for Microbiology (February 1999).
	AS	80	Derbyshire, V., and Belfort, M., "Lightning strikes twice: Intron-intein coincidence," <i>Proc. Natl. Acad. Sci. USA</i> 95:1356-1357, National Academy of Sciences of the USA (February 1998).
	AT	80	Dijkema, R., et al., "Cloning and expression of the chromosomal immune interferon gene of the rat," <i>EMBO J.</i> 4:761-767, IRL Press Limited (1985).

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09/517,466APPLICANT  
Hartley *et al.*FILING DATE  
March 2, 2000GROUP  
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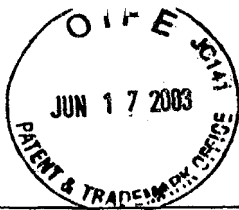
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AR	82	Francia, M.V., et al., "The IntI1 Integron Integrase Preferentially Binds Single-Stranded DNA of the attC Site," <i>J. Bacteriol.</i> 181:6844-6849, American Society for Microbiology (November 1999).
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AR	85	Hehl, R., et al., "Structural analysis of Tam3, a transposable element from <i>Antirrhinum majus</i> , reveals homologies to the Ac element from maize," <i>Plant Molec. Biol.</i> 16:369-371, Kluwer Academic Publishers (1991).
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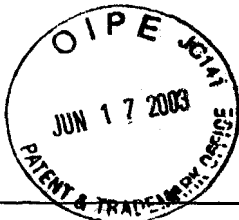
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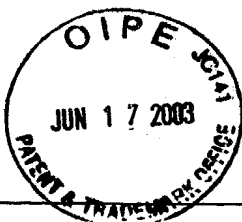
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
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	AR	94	Nagy, A., "Cre Recombinase: The Universal Reagent for Genome Tailoring," <i>Genesis</i> 26:99-109, Wiley-Liss, Inc. (February 2000).
	AS	94	Odell, J.T., et al., "Seed-Specific Gene Activation Mediated by the Cre/lox Site-Specific Recombination System," <i>Plant Physiol.</i> 106:447-458, American Society of Plant Physiologists (1994).
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	AR	95	Pal, S.K., et al., "Pl Plasmid Replication. Role of Initiator Titration in Copy Number Control," <i>J. Mol. Biol.</i> 192:275-285, Academic Press (1986).
	AS	95	Panke, S., et al., "Engineering of Quasi-Natural <i>Pseudomonas putida</i> Strains for Toluene Metabolism through an ortho-Cleavage Degradation Pathway," <i>Appl. Environ. Microbiol.</i> 64:748-751, American Society for Microbiology (February 1998).
	AT	95	Patel, P.H., and Loeb, L.A., "DNA polymerase active site is highly mutable: Evolutionary consequences," <i>Proc. Natl. Acad. Sci. USA</i> 97:5095-5100, National Academy of Sciences (May 2000).

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	AR	<u>96</u>	Perler, F.B., "InBase, the New England Biolabs Intein Database," <i>Nucl. Acids Res.</i> 27:346-347, Oxford University Press (January 1999).
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	AR	97	Powell, J., "Enhanced concatemer cloning-a modification to the SAGE (Serial Analysis of Gene Expression) technique," <i>Nucl. Acids Res.</i> 26:3445-3446, Oxford University Press (July 1998).
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AR	99	Sato, T., et al., "The <i>cisA</i> Cistron of <i>Bacillus subtilis</i> Sporulation Gene <i>spoIVC</i> Encodes a Protein Homologous to a Site-Specific Recombinase," <i>J. Bacteriol.</i> 172:1092-1098, American Society for Microbiology (1990).
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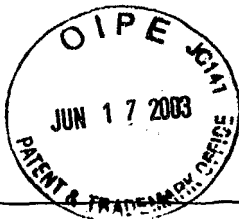
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>100</u>	Schnepf, E., et al., "Bacillus thuringiensis and Its Pesticidal Crystal Proteins," <i>Microbiol. Mol. Biol. Rev.</i> 62:775-806, American Society for Microbiology (September 1998).
AS	<u>100</u>	Segall, A.M., et al., "Architectural elements in nucleoprotein complexes: interchangeability of specific and non-specific DNA binding proteins," <i>EMBO J.</i> 13:4536-4548, Oxford University Press (1994).
AT	<u>100</u>	Shim, J., et al., "Distinct and Redundant Functions of $\mu$ 1 Medium Chains of the AP-1 Clathrin-Associated Protein Complex in the Nematode <i>Caenorhabditis elegans</i> ," <i>Mol. Biol. Cell</i> 11:2743-2756, The American Society for Cell Biology (August 2000).

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	AO						Yes No
	AP						Yes No

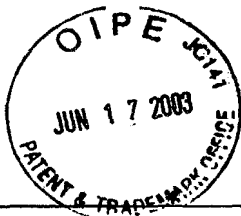
**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>101</u>	Skrally, F.A., et al., "Construction and Characterization of a 1,3-Propanediol Operon," Appl. Environ. Microbiol. 64:98-105, American Society for Microbiology (January 1998).
AS	<u>101</u>	Spinella, D.G., et al., "Tandem arrayed ligation of expressed sequence tags (TALEST): a new method for generating global gene expression profiles," Nucl. Acids Res. 27(e22):i-viii, Oxford University Press (September 1999).
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>102</u>	Stassi, D.L., et al., "Ethyl-substituted erythromycin derivatives produced by directed metabolic engineering," <i>Proc. Natl. Acad. Sci. USA</i> 95:7305-7309, National Academy of Sciences (June 1998).
	AS	<u>102</u>	Stellwagen, A.E., and Craig, N.L., "Mobile DNA elements: controlling transposition with ATP-dependent molecular switches," <i>Trends Biochem. Sci.</i> 23:486-490, Elsevier Science Publishers (December 1998).
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	AR	103	Sugiura, S., et al., "Minimal Essential Origin of Plasmid pSC101 Replication: Requirement of a Region Downstream of Iterons," <i>J. Bacteriol.</i> 175:5993-6001, American Society for Microbiology (1993).
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